

although the primary focus of the interview was on the independent claims. The cited and applied references were discussed, i.e., U.S. Patent No. 5,578,588 to Mattern et al. (hereinafter "Mattern") and U.S. Patent No. 5,880,117 to Arnold (hereinafter "Arnold"). Applicant's representative explained that neither Mattern nor Arnold anticipated the pending claims because neither of these references discloses a compound as recited in the claims, wherein a promoiety comprising a alkoxymethyl ether is appended to the 17 position of the substrate. In view of this lack of anticipation, Applicant's representative did not propose any claim amendments. The Examiner took these arguments under advisement, and did not state a formal position on them at the interview.

#### **Summary of Claims Status**

Claims 1-61 remain pending in this application. Claims 3-7, 11-13, 15-21, 29-33, 38-40, and 42-48 have been withdrawn, but may be rejoined upon allowance of a generic claim, *e.g.*, claims 1 and 26.

Claims 1,2, 8-10, 14, 22-28, 34-37, 41 and 49-61 are pending. In the Office Action, all are rejected under 35 U.S.C. § 102(b) as being anticipated by Arnold, and by Mattern. Claims 1 and 26 are independent.

#### **Claim Rejections – 35 U.S.C. § 102**

It is fundamental law that a reference, to anticipate a claim under Section 102(b), must fully disclose the invention as claimed, and thus each limitation of the claimed invention must be identically disclosed in the reference. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1574, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986).

Anticipation must be found in a single reference. *Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 726 F.2d 724, 726-27, 220 U.S.P.Q. 841 (Fed. Cir. 1984). The absence of even a single claim limitation from the cited reference negates anticipation under Section 102(b). *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715, 223 U.S.P.Q. 1264 (Fed. Cir. 1984). Because Arnold and Mattern each fail to meet this burden of anticipation under Section 102(b), these rejections are respectfully traversed.

Arnold and Mattern do not anticipate independent claim 1, nor is a *prima facie* case of anticipation set forth in the Office Action, for example, because Arnold and Mattern fail to disclose a compound for increasing the concentration of a parent androgen in a subject in vivo, wherein the parent androgen has a skeletal structure including a 17 position and the parent androgen further has a 17 $\beta$ -hydroxy group comprising a 17 $\beta$ -hydroxy oxygen appended to the 17 position and a 17 $\beta$ -hydroxy hydrogen appended to the 17 $\beta$ -hydroxy oxygen, wherein the compound comprises a substrate having the skeletal structure of the parent androgen including a 17 position corresponding to the 17 position of the parent androgen, and wherein a promoiety comprising an alkoxymethyl ether is appended to the 17 position of the substrate as a substitute for the 17 $\beta$ -hydroxy hydrogen, as recited in claim 1.

Arnold and Mattern disclose the testosterone precursors 4-androstenediol and androstenedione, respectively. Neither of these documents discloses a compound that comprises an alkoxymethyl ether promoiety appended at the 17-position. Arnold instead discloses a 4-androstenediol compound in which a hydroxyl

group is located at the 17-position. Mattern similarly discloses an androstenedione compound in which a ketone is located at the 17-position.

Arnold and Mattern similarly fail to anticipate independent claim 26, for example, based on the failure of these references to disclose a compound as recited in claim 26, which comprises a promoiety comprising an alkoxymethyl ether substituted at the 17 position of the substrate for the 17 $\beta$ -hydroxy hydrogen.

Based on statements made by the Examiner in the Office Action and during the March 12, 2003 interview, it appears that the Examiner has construed the instant claims as reading on any compound having the skeletal structure of a parent androgen, or capable of increasing the concentration of a parent androgen *in vivo*. Applicant respectfully submits that, in so construing the claims, the Examiner has impermissibly neglected to take into consideration the recitation of the claimed "promoiety comprising an alkoxymethyl ether," as recited in claims 1 and 26.

The United States Supreme Court has expressly stated that each limitation of a claim is deemed material to defining the scope of an invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). The "promoiety comprising an alkoxymethyl ether" limitation of claims 1 and 26 therefore may not simply be disregarded.

For these reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 102(b) rejections of claims 1 and 26 over Arnold and Mattern.

Applicant further respectfully submits that claims 2-25 and 27-61, being dependent from claims 1 and 26, respectively, and including all of the distinguishing features thereof, also are not anticipated by and are patentable over Arnold and Mattern for the reasons advanced above.

Applicant also submits that the invention as recited in claim 1 patentably distinguishes over Arnold and Mattern, for example, because these references fail to suggest or render obvious the invention as recited. As noted above, Arnold discloses a method of administering 4-androstenediol as a means of increasing testosterone levels in humans. Applicant finds nothing in Arnold that would have suggested to a person of ordinary skill in the art to make the necessary modification to the molecule, and more specifically to modify the group at the 17 hydroxy hydrogen position as recited in claim 1, to obtain a compound as recited in Applicant's claim 1. Arnold in contrast teaches that the use of 4-androstenediol, with an hydroxyl group at the 17 position, satisfactorily increases testosterone levels, and therefore would not have provided the necessary motivation and teaching to yield Applicant's invention.

Mattern similarly would not have suggested or rendered obvious the invention as recited in claim 1. Mattern, in disclosing a method involving the use of androstenedione, also fails to suggest to a person of ordinary skill in the art to make the necessary modification to that molecule, and more specifically to modify the group at the 17 hydroxy hydrogen position as recited in claim 1, to obtain a compound as recited in claim 1. Mattern merely teaches that the use of

androstenedione, with a ketone group at the 17 position, satisfactorily increases testosterone levels, and therefore would not have provided the necessary motivation and teaching to yield Applicant's invention.

Claim 26 patentably distinguishes over Arnold and Mattern for effectively the same reasons as those set forth above with respect to claim 1. Dependent claims 2-25 and 27-61 are not anticipated by, and patentably distinguish over, Arnold and Mattern for the reasons set forth herein, and in that they depend from and more specifically recite the invention of one of independent claims 1 and 26.

Applicant has not amended the claims, nor have the positions set forth herein been intended to nor had the effect of narrowing the protectable scope of the invention. They merely have drawn light to the deficiencies of the cited and applied references relative to the invention. Accordingly, no amendments or remarks have been made for any substantial reason related to patentability, and no estoppel applies.

### **Conclusion**

In view of the foregoing, Applicant requests reconsideration of the application and passage of all pending claims to issue.

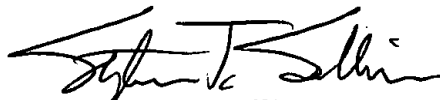
A Petition for Extension of Time and check for the petition fee are submitted concurrently herewith. If there are any other fees due in connection with the

prosecution of this application, please charge them to our Deposit Account No.

501,324.

Dated: June 24, 2003

Respectfully submitted,



Stephen T. Sullivan  
Reg. No. 32,444



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I hereby certify that this Response to Office Action No. 2 is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

